

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

X
DENISE BROUARD and GERALD BROUARD,

Plaintiff,

Index No.: 28560/05

-Against-

JAMES CONVERY, P.V. HOLDING CORP. and
AVIS RENT A CAR SYSTEM, INC.,

Affirmation

Defendants.

X

APOSTOLOS JOHN TSIOURIS, M.D., being duly sworn, deposes, says and affirms the truth of the following matters under penalty of perjury:

1. I am Chief of Neuroradiology at The New York-Presbyterian Hospital – Weill Cornell Medicine in New York, NY. My rank is Associate Professor of Clinical Radiology. I have 17 years of experience in an active clinical neuroradiology practice, in which my primary responsibilities are interpreting CT and MRI scans of the brain and spine. I also teach two courses at the Weill Cornell Medical School and have educated and mentored many residents and fellows in Radiology, Neurosurgery, Neurology, and Neuroophthalmology over the years. I have been actively involved in multiple research studies and have published over 100 peer-reviewed scientific papers, including papers on diffusion tensor imaging (DTI) in the setting of traumatic brain injury. I have also authored multiple chapters and a textbook on brain imaging. I routinely analyze and review DTI data sets for the purposes of neurosurgical brain tumor pre-operative planning. I am also co-chair of the American College of Radiology (ACR) TBI-RADS committee and co-chair of the ACR Data Science Institute (DSI) for Neuroradiology.

Lastly, I am also a committee member for the ACR Appropriateness Criteria for Head Trauma.

2. I have testified in other proceedings relative to my expert knowledge and I will testify in Court at any hearings and/or trials as required. All of my opinions herein are stated with a reasonable degree of medical and scientific certainty.

3. My duly sworn affidavit dated 8/22/16 and affirmation dated 7/16/18 submitted on the prior motions are annexed and incorporated by reference as though more fully set forth at length herein for the Court's convenience and to further set forth my qualifications. All of my prior sworn statements still hold 100% true. There are a few additional points on Plaintiff's motion to renew that need to be addressed.

4. I submit this affirmation in opposition to the Plaintiff's motion to renew the preclusion of DTI due to a lack of general acceptance for the purposes they intend to introduce DTI at the time of trial. The Plaintiff has provided multiple additional affidavits and affirmations that I have reviewed. The Plaintiff has decided to call them "new facts", but upon review it is established that none are actually "new facts". Rather, they are newly dated opinions/affidavits/affirmations based on documents and articles that existed at the time of the two prior motions in this matter and have been addressed in my prior affidavit and affirmation. Some were not written for this case and appear recycled from other cases, highlighting the continued controversy as to the acceptability of this technique. It remains my opinion, based on the current science/evidence to date, that DTI in the TBI patient setting is not generally accepted. It remains an investigational technique without common standards or

guidelines, unknown accuracy, or precision¹, and no probative value, that would run the substantial risk of confusing a jury.

5. The following points numbered 6 through 12 address Ms. Cannata's affirmation in support, where she incorrectly argues that Plaintiff proffers new facts which demonstrate: *(a) that the white paper is somehow invalid; (b) that the 2019 ACR-ASNR-SPR Practice Parameter endorses DTI to investigate the consequences of TBI; and (c) that DTI has become increasingly more available and utilized by the TBI community.*

6. She is wrong regarding her characterization of the 2015 ACR/AJNR white paper. This paper was conceived and written as an expert consensus, based upon thorough review of the existing literature. It was *peer-reviewed and endorsed* by numerous recognized national leaders in the field of TBI, who all reviewed and requested that their name be listed on the paper. It was commissioned and organized by the American College Radiology, which puts out the practice guidelines that Ms. Cannata references. It was reviewed and endorsed by the American Society of Neuroradiology (ASNR), American Society of Functional Neuroradiology (ASFNR), and the American Society of Pediatric Neuroradiology (ASPNR). Lastly, the Radiology Society of North American (RSNA), the largest and most influential Radiology society in the world, has posted an online position statement, that has been updated as recently as 6/25/20, and unchanged in content for years stating that "*advanced neuroimaging techniques, including MRI diffusion tensor imaging, functional MRI, MR spectroscopy, perfusion imaging, PET/SPECT and magnetoencephalography, are of particular interest in identifying further injury in TBI patients when conventional non-contrast*

¹ Precision (as defined in FDA filings for medical tests) expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under prescribed conditions. Precision encompasses metrics for defining the repeatability and reproducibility of a test. Precision is usually investigated using homogeneous, authentic samples.

head CT and MRI are normal, as well as for prognostication in patients with persistent symptoms. At present, there is insufficient evidence supporting the routine clinical use of these advanced neuroimaging techniques for diagnosis and/or prognostication at the individual patient level. This is the focus of ongoing research.”²

7. Ms. Cannata states that the practicing physician is more likely to be guided by *practice guidelines*. She goes on to cite the 2019 ACR-ASNR-SPR practice parameters of the performance of MRI of the brain. **I am familiar with these practice parameters and can say unequivocally that nothing contained therein addresses the issue presently before the Court, i.e., the use of DTI for diagnosis, prognoses, or assessment of TBI.** These practice parameters are specifically focused on routine structural MRI of the brain. DTI is only mentioned as an “extended indication for brain MRI.” Diffusion MRI, on which DTI is based, is discussed on page 4 with the statement “*diffusion imaging is essential for many indications, particularly in the assessment of infarction, abscess, epidermal lesion, active demyelination, and hypercellular neoplasm.*” **TBI is not mentioned in the entire document that Ms. Cannata incorrectly states endorses DTI in the setting of TBI. There is also not one reference or citation that includes DTI in the setting of TBI.**

8. Further to this point, the **American College of Radiology (ACR) Appropriateness Criteria for Head Trauma**³, created and periodically updated by the same organization that sets all standards and guidelines in Radiology and publishes the practice parameters, specifically address the use of DTI in traumatic brain injury. The Appropriateness Criteria establishes that “*overall, there is significant heterogeneity in*

² <https://www.rsna.org/media/position-statements>

³ <https://acsearch.acr.org/docs/69481/Narrative/>; The ACR Appropriateness Criteria® (AC) are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition. Employing these guidelines helps providers enhance quality of care and contribute to the most efficacious use of radiology.

fractional anisotropy measurements among both TBI and healthy subjects, with published data based primarily upon group-level analyses. Despite continuing improvements in scanner gradients and diffusion techniques (eg, intravoxel resolution of crossing fibers), there is insufficient evidence to support the routine clinical use of DTI at the individual patient level.”

This is the same conclusion reached by the white paper and for which Your Honor correctly based the decision upon to preclude the use of DTI.

9. Ms. Cannata states that DTI has become increasingly more available and utilized by the TBI community. However, there has not been a recent shift towards general acceptance of DTI in the clinic, but rather an increase in the introduction and reliance on DTI in litigation. One cannot restrain a physician from ordering, or a Radiologist from performing, a DTI study, but the fact that certain Radiologists are performing DTI exams, especially in the setting of litigation, does not render them generally accepted for assessing brain trauma in individuals. Unlike in litigation, there is no need to prove causation of a TBI in clinical care. The patient has a confirmed TBI with relevant objective and/or subjective symptoms which are focused upon for targeted rehabilitation. A normal or abnormal DTI scan in current practice does not alter therapy. DTI is never utilized for prognostication, since each patient is treated individually with maximum rehabilitative care, hoping for the best possible outcomes. DTI results are completely non-specific and can be indicative of *anything that can affect the brain during the patient’s lifetime*. If a DTI scan demonstrates regions of decreased FA that may indicate a difference in the individual’s axonal integrity when compared to well-matched controls, or if the study indicated a poor prognosis, the same targeted rehabilitative care would continue regardless of these results. Therefore, the results have no probative value to inform us about a specific alleged TBI. Likewise, if a DTI scan did not show such abnormalities,

targeted rehabilitative care would also continue regardless, because treatment is entirely planned upon clinical evaluation and symptomology expressed by the patient. DTI plays no role because it currently provides no additional information useful to diagnosis or prognosis. These facts were true at the time of the prior decisions in this matter to preclude DTI and have not changed.

10. There is concern in the medical community regarding the use of DTI to assess a TBI in the individual patient setting. Dr. Jonathan Silver, a Professor of Psychiatry at the New York University School of Medicine and a well-respected TBI expert, wrote in a 2012 article that “*evidence indicates that a positive expectation of recovery significantly predicts prognosis, and many unexplored factors may influence symptoms and recovery. Will the finding of an abnormality on DTI—which has no bearing on treatment decisions or interventions, since those are symptom based—affect recovery?*” and that “[current] studies do not yet provide us with a gold-standard clinical diagnostic measure for TBI.”⁴ Therefore, performing a DTI and telling a patient that he has “brain damage” may actually be counterproductive to their recovery, and therefore is not done in clinical practice. Because a small number of rogue practices perform DTI in the setting of personal injury litigation does not make the technique any more accurate, precise, or generally accepted by the medical and scientific community.

11. Ms. Cannata notes that physicians can order DTI studies for TBI patients at Stanford and Duke. Unfortunately, she is incorrect about Dr. Whitlow’s academic affiliation – he is currently the Chief of Neuroradiology at Wake Forest - not Duke. Regardless, she specifically omits how and why these studies are being ordered, performed, and interpreted.

⁴ Jonathan Silver. Diffusion Tensor Imaging and Mild Traumatic Brain Injury in Soldiers: Abnormal Findings, Uncertain Implications. *American Journal of Psychiatry* 2012

You can order a DTI study at an academic institution for any number of reasons, after all it is safe to perform on humans and can be used to produce a high signal to noise diffusion weighted anatomic trace image, which has numerous diagnostic indications. DTI scans can also be utilized to perform grossly anatomic white matter tractograms for neurosurgical guidance, unrelated to TBI. However, Stanford, Duke, *and* Wake Forest do not perform qualitative or quantitative DTI analyses for the diagnosis, assessment, or prognostication in the setting of TBI. Of note, Dr. Provenzale is one of the senior neuroradiologists (and former Chief of Neuroradiology) at Duke; he has supported numerous legal Daubert hearings to exclude DTI for many of the same reasons outlined in my affirmations/affidavits. I am also not surprised that a technologist at Duke told Dr. Mahan that they have an MRI/DTI protocol for head trauma, most likely for investigational/research purposes, as we have at my academic institution. This is because DTI research in the TBI setting continues in the neuroradiological community and such protocols are necessary to conduct that research. We continue to conduct research with the hope that future advancements may allow for its use in patient care, a goal that has not been realized to date.

12. Most of the centers Ms. Cannata references in her affirmation that utilize DTI clinically advertise directly to the legal community and others advertise for research purposes. Regardless, there are many more that *do not* perform DTI for the clinical assessment of TBI, such as NYP-Cornell, NYP-Columbia, NYU, University of Florida, Massachusetts General Hospital, Johns Hopkins, Stanford, Duke, Wake Forest, UCSF, UCLA, University of Michigan, Northwestern, Mayo Clinic, Houston Methodist, Washington University in St. Louis, etc. Regardless, the decision to utilize DTI clinically does not negate the consensus in the medical community that DTI is not generally accepted for use in individual TBI patients.

13. Plaintiff continues to attack the credibility of the white paper, not by relying on any new facts, but rather by presenting the same failed opinions they expressed about its credibility at the time of the prior two motions. Dr. Jennifer C. van Velkinburgh's affidavit submitted for *Reichman v Whirlpool Corp* outlines her opinion on the white paper. This issue was addressed in my prior affidavit and affirmation. None of her opinions are based on any new facts or information. She states that "*White Papers are opinion pieces and non-scholarly/non-science publications because they 1) bypass traditional peer review, 2) do not adhere to the international standards and norms of scholarly/science publication, and 3) present biased data in a non-transparent manner to manipulate a reader's understanding of a topic.*" **This is not true.**

14. A white paper is a report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision. The white paper was commissioned by the American College of Radiology (ACR), which also publishes the Practice Parameters for brain MRI and the Appropriateness Criteria for imaging TBI. The ACR sets standards and guidelines for medical imaging (which are often used as legal standards in medicolegal proceedings) and monitors radiology practices across the nation for imaging quality and radiation safety. The ACR staff curated over 900 current articles on imaging in TBI and ranked them by impact and level of evidence. Approximately 160 articles with the highest level of evidence were included as references for the white paper. The paper was written jointly by 5 main authors and then sent out to all the ACR Head Injury Institute (ACR-HII) members for edits and comments. After incorporating numerous edits from the long list of ACR HII reviewers, the finished paper was sent to the ASNR, ASFNR, and

ASPNR societies for endorsement. It was an ACR society-initiated paper that sought to synthesize and summarize the current literature on a complex increasingly controversial topic.

The only member of the ACR-HII that did not endorse the paper was Dr. Lipton.

15. In Dr. Peyster's affirmation, he states that "*in my opinion, DTI's clinical and forensic application should be limited to facilities that can demonstrate the high-quality interpretive criteria comparable to that applied at Montefiore.*" This unilateral opinion on how and when it should be used does not equate to general acceptance by the relevant medical community. He expresses nothing more than the opinion that Montefiore can assess DTI studies better than other facilities. I disagree with this opinion since it is not based upon any facts or evidence that would supplant the general consensus of the relevant medical communities that DTI is not appropriate for such clinical use. I point out that none of the other physicians that provided affidavits to support the instant motion to renew "live up" to Montefiore's standards. For example, Drs. York and Snyder perform visual qualitative interpretations of color-coded FA maps and tractograms, which is widely known to be an incorrect and inaccurate method of interpreting DTI. Dr. Snyder also performs region of interest (ROI) measurements of the FA values in the corpus callosum but does not describe any normal comparison group. Additionally, he exports his patient's DTI data to the company Mindset for a whole brain voxel-based analysis similar to Dr. Lipton's, but utilizing a control group scanned on different MRI scanners. Dr. Gonzales-Toledo has used "normal" FA values obtained from the literature for his ROI analysis of the corpus callosum, even though it is widely understood and accepted that the DTI control group must be well matched to the subject and must be scanned on the same scanner with the same DTI protocol parameters to provide a valid reference. I would opine that these three doctors who use widely disparate DTI

acquisition and analysis methods from Dr. Lipton, highlighting the lack of standards and guidelines for DTI, would not be thought of by Drs. Peyster or Lipton as demonstrating “high-quality interpretive criteria.” Thus, if Dr. Peyton’s opinion was theoretically true, then the consequential result would be to negate the other submitted affidavits annexed to Plaintiff’s motion to renew. However, his opinions are not new facts as explained below, and these other affidavits individually do not stand up to merit on their own accord.

16. Dr. Peyster also points out that advanced neuroimaging techniques should not be used routinely for the assessment of TBI, but claims they can be sometimes useful. He cites the patient who has normal conventional brain imaging, yet their post-concussion symptoms persist rather than resolve as expected; in this case the *“physician seeks DTI to investigate whether white matter injury accounts for chronicity.”* Unfortunately, this is the equivalent of performing a controversial and expensive test simply for morbid curiosity. Regardless of the DTI results, the treatment/prognosis remains unchanged. If anything, the DTI results may hinder clinical improvement due to the psychological impact of knowing you have “brain damage”. Also, just because a few rogue physicians use DTI clinically does not make it generally acceptable by the medical community at large, which is supported by the white paper, ACR Appropriateness Criteria, and the RSNA position statement.

17. Dr. Peyster states that *“despite DTI’s high sensitivity to detection of white matter impairment, it is not sufficiently specific to make a stand-alone diagnosis”* and *“neither CT or MRI is sensitive enough or specific enough to be a stand-alone diagnostic of concussion/mTBI.”* This statement is confused – DTI assesses statistical differences in water motion along white matter tracts between a subject and a well-matched normal control population. Those statistical differences can be secondary to *anything that affects the brain*

from the womb up to the time of the study – remote trauma, hypertension, diabetes, strokes, alcohol or drug use/abuse, training, psychiatric disease, infections, handedness, education, etc.

Therefore, DTI is the equivalent of a Covid-19 test that is positive for any virus you have had at any point in your life but cannot tell you which virus or when you were infected (i.e., highly sensitive but not specific). Since DTI tends to be interpreted as “abnormal” in a large percentage of subjects tested, it becomes useless in both clinical care and as probative evidence in court. Even worse, it becomes misleading when applied as a supportive test for the diagnosis or assessment of mTBI. Regardless, the diagnosis of concussion/mTBI is made on clinical grounds at the time of the head injury, and no advanced imaging can manufacture an alleged mTBI. Lastly, anatomic CT and MRI scans are not performed to support the diagnosis of mTBI – they are performed to determine if the patient needs urgent neurosurgical or ICU care. Although they are less sensitive than DTI, they are far more *specific* in identifying evidence of acute, subacute, and chronic traumatic brain injuries. There are well described and non-controversial specific patterns of brain injury (subarachnoid hemorrhage, extra-axial hematomas, hemorrhagic cortical contusions, hemorrhagic axonal injuries, arterial dissections, infarctions, etc.) that are clearly identified on structural CT/MRI scans.

18. Dr. Peyster states that *“as a practicing neuroradiologist, I am not constrained by the recommendations of a ‘white paper’...the same can be said for a media position statement.”* However, we are not debating whether a single physician can do whatever they want in their clinical practice. We are debating whether DTI is accurate, precise, and generally accepted for clinical practice, which it is not. If the standard was whether an individual doctor unilaterally decided to use a test clinically, then every new technology/method would be “generally accepted”, even if the overwhelming general consensus states it is not. The white

paper was commissioned to review the available scientific research and obtain a general consensus to be used as a guide for the community as to the general acceptance or lack thereof of various available neuroimaging methods (including DTI) pertaining to individual TBI assessment.

19. Plaintiff inappropriately relies on the affidavit of Dr. Gerald York. He stated in the *Marsh v. Celebrity Cruises* case that “*DTI MRI has been used in clinical neuroradiology by numerous medical centers, most notably the Departments of Defense in the evaluation, diagnosis and management of mild TBI of service men and women, as part of a protocol of neuroimaging, as well as correlation of clinical findings. I was involved in the development, evaluation, distilling and publication of the DOD/Centers of Excellence protocol for clinical evaluation of mTBI...*” However, the VA/DOD posts online their “Clinical Practice Guidelines for the Management of Concussion – Mild Traumatic Brain Injury.”⁵ On page 24, it specifically states, “*While many advanced neuroimaging techniques show promise in the diagnosis of mTBI, there is no evidence to support routine use in this population later than seven days after the event. A meta-analysis of MRI diffusion tensor imaging (DTI) in the post-concussion population (time since injury of three days to eight years) showed fractional anisotropy (FA) reduction in several brain regions that have been associated with brain injury. However, many of the studies had significant methodological problems, particularly problems with selection of control groups that adequately control for potential confounders. In a military cross-sectional study with the same FA findings (and the same methodological problems with control selection), only 40% of post-concussion patients had abnormalities on DTI, making sensitivity inadequate for routine use at this time. In addition, these studies have not linked DTI findings with clinical presentation or outcomes.*” Other than the information

⁵ <https://www.healthquality.va.gov/guidelines/rehab/mtbi/>

above, which supports the preclusion of DTI, Dr. York does not offer any new or unique facts not available at the time of the two prior motions in this matter.

20. Most of Dr. Duncan (from Zwanger-Pesiri) points have already been addressed and his affidavit fails to present any new factual information that was unavailable at the time of the two prior motions. However, Dr. Duncan does state that “*Zwanger-Pesiri offers DTI to its patients for suspected concussion or other forms of TBI...prescriptions for [DTI] studies most commonly come from their treating neurologist.*” This statement is irrelevant to this argument. There is no medical necessity to image a patient with a “suspected” concussion or a more severe TBI, *since the diagnosis is made on clinical grounds and the therapy is based on symptomology*. I would opine that far more likely, these patients are being referred to Zwanger-Pesiri from neurologists who need “proof” of a concussion in the setting of active litigation, knowing that utilizing a test that has a high likelihood of being “positive” due to its known high sensitivity, but low specificity will support their case. This is clearly evident by the newly added “ZP Personal Injury Division” (<https://www.zwangerpesiri.com/personal-injury/>) on his practice’s website that caters specifically to personal injury attorneys. Also, it is incumbent on Dr. Duncan as a neuroradiologist to educate any referring neurologist of the inaccuracy and imprecision of DTI, since they are clearly are not the experts in the constantly evolving field of DTI for TBI.

21. Dr. Duncan also states that “*he can attest that within the radiological community, DTI is valid and appropriate in the evaluation of TBI as part of a multifactorial assessment of the possible neurobiological consequences of head trauma.*” This is clearly a false statement given the multiple provided published statements by all the major radiologic societies (ACR, RSNA, ASNR, ASFNR, and ASPNR) and the VA/DOD, plus that DTI is not

recommended by the ACR Appropriateness Criteria for imaging head trauma. He offers no new facts and simply reiterates Dr. Lipton's opinions, already submitted with prior motions.

22. Dr. Duncan again references the ACR Practice Parameters for MRI, stating that "*the ACR-ASNR-SPR practice guidelines clearly envision the use of DTI*" and that "*Dr. Max Wintermark is listed as a member on the Committee for the Neuroradiology Practice Parameters, which would seem to indicate his agreement with the ACR-ASNR-SPR endorsement.*" **Again, the Practice Parameters are for structural MRI of the brain, and do not address DTI or TBI. If DTI was an accepted technique with defined standards and guidelines it would have its own ACR Practice Parameters. Instead, the ACR Appropriateness Criteria for Imaging TBI, of which I am a committee member and co-author, specifically address and reject the use of DTI in the setting of TBI.**

23. Dr. Duncan is purposefully attempting to confuse the issue with the erroneous point that the white paper states incorrectly that DTI has not been standardized, implying that structural MR imaging has been standardized. He is correct that the pulse sequence parameters used by different manufacturers and sites for acquiring structural and functional imaging sequences are not identical; *however*, any neuroradiologist can visually assess a structural MR sequence and determine if it has been performed appropriately and whether it is degraded by artifact. In fact, the ACR periodically requests imaging centers such as Zwanger-Pesiri to transfer structural imaging examinations to their central servers for review and quality assurance; Zwager-Pesiri proudly has the ACR "stamp of approval" for structural imaging quality on their website (the ACR Diagnostic Imaging Center of Excellence stamp). The ACR Practice Parameters for MRI, which are repeatedly referenced by multiple Plaintiff's affidavits, specifically state "*Magnetic resonance imaging (MRI) is a proven and well-*

established imaging modality in the evaluation and assessment of the brain. MRI of the brain is the most sensitive technique available because of its high sensitivity in exploiting inherent contrast differences of tissues as a result of variable magnetic relaxation properties and magnetic susceptibilities. MRI is a rapidly evolving technology, and ongoing technical advancements will continue to improve the diagnosis of brain disorders. This practice parameter outlines the principles for performing high-quality MRI of the brain.” Again, there are no practice parameters published for DTI since there are no standards or guidelines for its acquisition, post-processing, or analysis. Also, unlike anatomic MRI sequences, DTI is being used as a *quantitate metric* in this setting; therefore, quality assurance is even more paramount. An appropriate analogy would be glucometers at medical laboratories, which periodically undergo quality assurance testing for accuracy and precision in measuring blood glucose levels. This is simply not done with DTI across different sites.

24. Dr. Duncan’s comment concerning the greater standardization of DTI is also nonsense; **he cites the same outdated AFNMR recommendations published online in 2012, which are also based on expert consensus similar to the ACR white paper that he criticizes in his same affidavit. In addition, the major difference between the AFNMR guidelines and the white paper is that the AFNMR guidelines were written by just 6 experts and have never been endorsed.** Again, this is not new factual information unavailable at the time of the prior motions.

25. Furthermore, Dr. Pratik Mukherjee (Professor of Radiology, UCSF), who was on that AFNMR committee and is a founding member of the multi-center TRACK-TBI consortium *does not endorse clinical DTI*. He actually debated Dr. Lipton at the RSNA meeting in 2015 as to why DTI cannot be used clinically in individuals for the assessment of

TBI⁶. Dr. Mukherjee stated during this live debate with Dr. Lipton (quoted from RSNA online) that “*one point of controversy surrounding the use of DTI centers on the question, ‘Is this really helpful on an individual patient basis as far as being able to diagnose a mild TBI concussion and say something useful about how a patient will progress afterwards?’*” He also stated that “*this really hasn’t been validated yet in multi-center trials that are designed to measure its specificity, sensitivity and utility of predicting outcomes in patient—all of the things you would want in a scientific test.*”

26. Another key author of the 2012 ASFNR guidelines, Dr. Christopher Filippi (Vice Chair of Radiology Research at Northwell Health and Professor of Radiology at Hofstra) was the senior author of a 2014 paper in the *American Journal of Bioethics* on the use of DTI in TBI titled “The Potential for Medicolegal Abuse: Diffusion Tensor Imaging in Traumatic Brain Injury” that concluded “*Although the technology and theory that supports DTI is provocative and exciting, we argue that expert testimony that confidently relies on DTI is highly problematic. In this article, we discuss the current limitations inherent in acquiring and analyzing DTI data; list problems especially with specificity that limit DTI’s appropriateness in single-subject instances; and provide a brief history of the misuse and abuse of neuroimaging in mental illness and brain injury. We conclude with a plea for healthy skepticism regarding the value of these latest modalities in medicolegal settings, especially given the nature of their frequently visually spectacular impact on judges and jurors.*”⁷

27. Lastly, Dr. Duncan concedes that DTI lacks specificity, but claims many other medical tests including CT and MRI also lack specificity, which is false. On a structural MRI, when I identify a 3 cm irregular and heterogeneously enhancing hemorrhagic mass within the

⁶ <https://www.rsna.org/news/2015/february/is-dti-for-mild-traumatic-brain-injury-ready>

⁷ Wortzel et al. The Potential for Medicolegal Abuse: Diffusion Tensor Imaging in Traumatic Brain Injury. *American Journal of Bioethics* 2014

frontal lobe of a 65-year-old patient, I can ascertain he has a glioblastoma, which is a malignant brain tumor. The neurosurgeon then resects that mass and I get immediate feedback regarding if my diagnosis was correct. Similarly, when interpreting a lumbar spine MRI on a 30-year-old UPS driver with acute radiating back pain following lifting a heavy box at work, I can see the large extruded disc herniation impinging a nerve root. The orthopedic surgeon then performs a discectomy and I get feedback regarding if my diagnosis was correct. If Dr. Duncan reviewed these same studies he would most likely make the same conclusions. Therefore, structural MRI, unlike DTI, has high specificity (with validation) and precision, qualities that are both necessary in a valid medical test, especially one that is being introduced as evidence in court proceedings.

28. I reviewed the affidavit produced for the *Domenica Fusco v Scott Levine* case in Shreveport, LA, by Dr. Gonzales-Toledo from Louisiana State University; Dr. Gonzales-Toledo was trained as a neurosurgeon many years before the advent of DTI. He is also not board certified in Diagnostic Radiology or Neuroradiology. His affidavit does not provide the Court with facts or evidence that was unavailable at the time of the prior motions in this matter. Also, many of Dr. Gonzales-Toledo's comments are irrelevant, regarding cortical thickness mapping (CTM), another unproven technique, and are not applicable to DTI or the issues in this case.

29. Dr. Hugo Cuellar is the Chairman of Radiology and a Professor of Neurosurgery at LSU, and Dr. Gonzales-Toledo direct superior. Dr. Cuellar does not believe there is sufficient evidence supporting the use of DTI for the assessment of TBI. This is also the position of the LSU Medical School.

30. Dr. Gonzales Toledo states that DTI has a very low error rate when used in individuals, for which he provides no citations. The true error rate of DTI for mTBI is unknown.

31. Dr. Gonzales-Toledo states that the 1.5 Tesla GE MRI scanner that he uses for his DTI scans “*is certified by the American College of Radiology and is checked for accuracy by a certified technician every 2 years.*” He fails to mention that the ACR certification is only for anatomic imaging, as noted above, and the technician is typically an engineer that assesses the correct functioning of the hardware rather than the accuracy of the DTI data acquisition.

32. Dr. Gonzales-Toledo incorrectly claims DTI is used by the US military in diagnosing TBI; this is simply false per the above discussion on the VA/DOD Clinical Practice Guidelines for the Management of Concussion – Mild Traumatic Brain Injury.

33. Dr. Gonzales-Toledo states that DTI is FDA approved. The FDA has only assessed the safety of DTI in humans. The FDA has never approved the use DTI for the assessment of TBI and did not assess the accuracy or precision of the technique. If DTI did not have FDA approval, research on DTI could not be performed. **In fact, the only imaging study the FDA recommends for TBI clinical trials is a non-contrast CT scan.**

34. Dr. Gonzales-Toledo cites multiple papers that he professes validate DTI to detect brain damage; the papers he cites existed and were reviewed during the drafting of the white paper and were available before submission of the first motion in this matter. His affidavit offers no new factual information that did not exist prior to the first two motions.

35. Dr. Gonzales-Toledo claims he established “*normal values with corroboration by autopsy, operatory findings, and clinical correlation.*” I find this statement difficult to believe given that patients with mTBI typically do not have brain surgery or autopsies after

their concussion. He does not cite any original research to prove this incredible statement. A Google Scholar search does not come up with any original scientific research published by Dr. Gonzales-Toledo in the field of DTI and TBI.

36. I reviewed the affidavit produced for the *James Michael Hall v Landstar Ranger* case in Lafayette, LA written by Dr. William Brennen, who is a Neurosurgeon with no expertise in the acquisition, processing, or analysis of DTI for TBI. His affidavit fails to provide this Court with any new facts or evidence. For instance, Dr. Brennen cites Dr. Lipton's 2013 article "A Decade of DTI in Traumatic Brain Injury: 10 years and 100 Articles Later." This article was submitted and addressed on the prior motions in this matter. More importantly, this is a non-scientific *review article* that does not contain any original research and does not even support the use of DTI in individuals for the assessment of TBI. It appears hypocritical that the Plaintiff relies upon and deems credible a non-scientific review article written by their expert, but erroneously attack the credibility of the white paper, which was commissioned by the ACR and endorsed by numerous Neuroradiology societies of which Dr. Lipton is a member. Essentially, Plaintiff is asking the Court to ignore the more recent and expansive white paper that only Dr. Lipton refused to endorse and instead rely solely on his older less expansive review paper that was not similarly endorsed.

37. I would like to address the affirmations of Drs. Safdieh, Golzad, and Greenwald jointly. None of these doctors are Neuroradiologists or have any expertise in acquiring, post-processing, or analyzing DTI data, and therefore their opinions are not pertinent to this motion. They are all physicians who order DTI scans, believing that this test can "support" the diagnosis of a TBI in the "appropriate clinical setting," when they are all aware that in clinical practice you do not need to support the diagnosis of a TBI. They are also

all aware that the DTI results have no bearing on the treatment of their patients. None of these affirmations cite or include any new information, papers, or data that was unavailable during prior motions in this matter.

38. Dr. Golzad incorrectly states that DTI scans are reimbursed by most insurance carriers – that is simply incorrect. No insurance carrier reimburses DTI scans. There is no ICD-10 code for DTI in the setting of TBI. Insurance reimburses only the structural MRI scan; any DTI performed or analyzed during that scan does not result in any additionally reimbursement. He also discusses the “facts on the ground” as they exist in 2020 but offers no documents that support what amount to simply his erroneous and unsubstantiated “facts”.

39. Dr. Greenwald states that he uses DTI clinically for patients who present to him with clinical histories, signs, and symptoms of TBI. In that case, what does he need a DTI scan for in the clinical setting? His patients seem to have suffered a TBI, and therefore it does not need to be proven. The DTI results would not change the severity or the clinical management.

40. Dr. Safdieh is a colleague of mine at NYP-WCMC. He is not part of the Concussion Consortium at NYP-WCM. He has no experience in acquiring, analyzing, or interpreting DTI and as far as I know has never directly participated in any TBI research at NYP-WCM. He is well aware of the fact that NYP-WCM does not perform clinical DTI scans for the assessment of TBI; DTI scans at NYP-WCM are only acquired for research purposes. At NYP-WCM, the chairman of Neurology (Dr. Matthew Fink) and Neurosurgery (Dr. Phillip Stieg), both wholeheartedly agree with the general medical consensus that DTI is not ready to be used in individual for the assessment of TBI. Dr. Safdieh states in point 9 that “DTI is well-established, reliable, peer-reviewed...”, however, he cites no literature to support this claim

and his own institution and Concussion Consortium do not believe that DTI can be used for the individual assessment of TBI. Otherwise, all his opinions have already been addressed and nothing he states is a new fact since the Plaintiff's prior two motions.

41. Recently, Dr. Martha Shenton (Professor and Director, Psychiatry Neuroimaging Laboratory, Department of Psychiatry, Brigham and Women's Hospital, Harvard Medical School) reviewed the application of DTI analysis in individual patient, focusing on its use in litigation. She concluded: *"We thus caution against the premature use of new advances in imaging such as DTI, before standards are established in the clinical arena, which are well informed and validated in the research arena. Judges, who are now gatekeepers with respect to evaluating the admissibility of evidence, need also to be informed with respect to the sensitivity and specificity of scientific measures, to issues of standardization, to appropriate methods of analyses, etc. in the use of DTI as evidence of mTBI in the courtroom. [DTI] probative value is also not clear as it may be both prejudicial and misleading given that standardization is not yet established in either the clinic or in the courtroom, and thus it may be premature for use in either. There are also concerns, as noted previously, regarding the methods and analyses that have been used to provide quantitative evidence in legal cases. Finally, we also caution against the use of neuroimaging techniques such as DTI in the courtroom as we are not yet at the tipping point where these advances provide important and meaningful data with respect to their probative value. There is much to be learned and much to support evidence of subtle brain injury that will move from the purview of research in the near future. Additionally, we note that while it may be premature now to bring new imaging tools into the courtroom, we should remain hopeful that such tools*

will be ready in the very near future. At this time, however, the gold standard remains the clinical interpretation by the neuroradiologist.“⁸

42. With regard to Dr. Lipton’s January 2021 affirmation, Dr. Lipton specifically states that from 2013 to the present, Montefiore’s DTI technology and analysis has remained essentially the same. I would like to stress that Dr. Lipton published an article in 2015 that specifically interrogated whether the whole brain DTI template utilized for whole brain voxel-based analysis should be based on an anatomic atlas or the subject of interest. He determined that the “*atlas-based registration approach suffers from potentially important errors of accuracy due to misregistration of the subject’s brain to the atlas*” and his new subject-based approach “*results in a significant reduction of erroneous findings that arise from these registration errors.*”⁹ Notably, Plaintiff’s DTI scans were both analyzed in 2008 and 2014 while this alleged new more accurate subject-based technique was still being investigated by Dr. Lipton. Also, as I detailed in my original affirmation, Dr. Lipton and the Plaintiff claim that DTI has been generally accepted for over a decade and rely on peer reviewed papers from the mid 2000’s and forward. Therefore, Dr. Lipton’s 2015 *PLOS ONE* article establishes that the state of DTI science and research has continuously evolved and changed since 2003. Therefore, any prior conclusions of the accuracy and precision of DTI in individual subjects are no longer generally accepted. Consequentially, any reliance on prior Court Decisions regarding DTI are based on outdated information.

43. I address the remainder of Dr. Lipton’s January 2021 Affidavit in a Supplemental Affidavit, as it addresses a separate issue regarding type of data that needs to be

⁸ Shenton et al. Mild traumatic brain injury: Is DTI ready for the courtroom? *International Journal of Law and Psychiatry* 2018

⁹ Suri et al. Subject Based Registration for Individualized Analysis of Diffusion Tensor MRI. *PLOS ONE* 2015

disclosed if DTI was generally accepted. As DTI in this matter is precluded, the issue as to the data needed is moot and would only need to be addressed if DTI were admissible.

44. Please take notice that any issue not addressed in this affidavit is not to be taken as a consent to the Plaintiff's position. My original affirmation debunks all of their theories. This instant affidavit is submitted to inform the Court of new information not in existence at the time the original motions were submitted that supports preclusion, while explaining how Plaintiff has again relied on older information both available and addressed in the prior motions. It is submitted to stress some of the very important points and inaccurate arguments submitted by the Plaintiff. I again refer the Court to my annexed original affirmation/affidavit, read in conjunction with this affirmation, for a complete discussion as to why DTI is not generally accepted.

Dated: 11-June-2021

A handwritten signature in black ink, appearing to read "J. Tsiouris", is written over a horizontal line.

Apostolos John Tsiouris, M.D.